COMMONWEALTH of VIRGINIA
Department of Health
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RICHMOND, VA 23218

M. Norman Oliver, MD, MA
State Health Commissioner

TTY 7-1-1 OR
1-800-828-1120

December 13, 2019

Thomas J. Stallings, Esquire
McGuire Woods, LLP
800 East Canal Street
Richmond, Virginia 23219

RE: CERTIFICATE OF PUBLIC NEED
(COPN or "Certificate")
REQUEST NUMBER VA-08391
LewisGale Medical Center, LLC
Salem, Planning District (PD) 5
Introduction of Neonatal Special Care Services

Dear Mr. Stallings:

In accordance with Article 1.1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 *et. seq.*) of the Code of Virginia, I have reviewed the application captioned above and the record compiled in relation to the project proposed in that application. As required by Subsection B of Virginia Code § 32.1-102.3, I have considered all matters that must be taken into account in making a determination of public need.

I have received and reviewed the findings, conclusions, and recommended decision of the adjudication officer who convened the informal fact-finding conference to discuss the application and who reviewed the administrative record pertaining to the proposed project. I also have reviewed the staff recommendations of the Division of Certificate of Public Need. I decline to adopt either recommendation in its entirety. Instead, I find that a public need for the project has not been demonstrated for the reasons stated below.

I. The project is not consistent with the State Medical Facilities Plan ("SMFP").

In order for a project to be approved, it must be consistent with the most recent applicable provisions of the SMFP. Va. Code § 32.1-102.3(A). After review of the record, I find that the proposed project is not consistent with the SMFP.

A. Driving Time

Pursuant to 12VAC-230-940(B), specialty and subspecialty neonatal special care services should be located within 90 minutes driving time one way under normal conditions of

hospitals providing general or intermediate level newborn services using mapping software as determined by the Commissioner. This standard is already met. Approval of the proposed project would not significantly increase access in this manner.

B. Need for New Services

Pursuant to 12VAC5-230-970(A), existing specialty level newborn services as designated in 12VAC5-410-443 should achieve 85% average annual occupancy before new specialty level newborn services can be added to the health planning region. I acknowledge that the definition of "beds" in the SMFP excludes bassinets, that bassinets are not COPN approved or otherwise licensed as to the number of bassinets, that hospitals may increase or decrease the number of bassinets at will, and that the availability and occupancy of existing bassinets often may be arbitrary. I do not necessarily agree that this renders the SMFP provisions meaningless, but I agree with the general consensus of the DCOPN staff report and the adjudication officer's recommendation that this provision is not instructive in this case.

C. Minimum Size of Unit

The SMFP states that specialty level newborn services as designated in 12VAC5-410-443 should contain a minimum of 18 bassinets. 12VAC-230-970(B). This standard is not met. LewisGale is requesting approval for only an 8-bassinet unit. Evidence of record demonstrates that all but 3 of Virginia's 14 existing specialty level units have fewer than 18 bassinets; but the fact that providers have decreased the number of bassinets in their specialty level newborn services after obtaining their COPN does not change the SMFP requirement. Although I acknowledge that the number of bassinets can change at will, LewisGale Medical Center is requesting less than half the required number of bassinets under this provision. Neonatal services, as they progress in acuity and level, are highly utilization sensitive. Unnecessary addition of services, despite any other benefits the project may have, could have a harmful effect on the quality of services available and provided.

D. Effect on Existing Services

The SMFP states that proposals to establish specialty level services as designated in 12VAC5-410-443 shall demonstrate that service volumes of existing specialty level newborn service providers located within the travel time listed in 12VAC5-230-940 will not be significantly reduced. 12VAC-230-970(D). I find that the record demonstrates there will be some reduction in both obstetrical and neonatal admissions. The DCOPN staff report noted concerns that utilization at Carilion Roanoke Memorial Hospital would be negatively impacted such that it will experience a decline in both specialty and intermediate level admissions.

For the reasons discussed, I find that the proposed project is not consistent with the SMFP; and, therefore, the application for the proposed project must be denied. Va. Code § 32.1-102.3(A). It is not necessary to address the remaining statutory factors; but for the sake of clarity, I will address the other reasons I find that a public need does not exist for the proposed project.

II. There is no public need for the proposed project.

A. The project will not increase access to needed services.[1]

Carilion Roanoke Memorial Hospital is recognized as the regional perinatal center in southwestern Virginia and is equipped, staffed, and organized to provide 60 subspecialty level nursery bassinets. It has available an average of 18 specialty care bassinets on a daily basis. It is located just fifteen minutes from LewisGale Medical Center.

Approval of the project would increase the number of women with high-risk pregnancies who could be admitted to their facility. These women, however, have access to a facility 15 minutes away that can provide both high-risk obstetrical and subspecialty neonatal care. The argument that health outcomes would improve with approval of the project is not substantiated with data. The record contains anecdotal data only. Additionally, while approval of the project could decrease transfers for some LewisGale Medical Center patients, it could increase transfers for patients at other hospitals. A nearby hospital without specialty services could transfer its patient to LewisGale Medical Center but then require a second transport to Carilion Roanoke Memorial Hospital should the patient's condition deteriorate.

Furthermore, evidence of record demonstrates that the LewisGale Medical Center's amount of charity care was just 1.10% in 2016, less than half the regional average of 2.8%. Additional assurances are needed regarding emergent access for vulnerable population.

B. The needs of the residents are met already.[2]

The proposed project has ample public support and no known opposition. The record includes letters of support from constituents, Virginia Senate members, Virginia House of Delegates members, and other local leaders. The neonatologists who currently staff Carilion Roanoke Memorial Hospital's subspecialty level services also support the project. These facts, while helpful in gauging public opinion, are not dispositive of a public need determination.

[1] Va. Code § 32.1-102.3(B)(1)

[2] Va. Code § 32.1-102.3(B)(2)

The adjudication officer noted that legislation was introduced recently to the General Assembly regarding specialty level neonatal care services in Planning District 5.[3] The Commissioner notes the proposed legislation; but it, too, is not dispositive in the public need determination.

A reasonable alternative exists to the proposed project. Despite a history of a recent bad outcome, the status quo is a reasonable alternative. Carilion Roanoke Memorial Hospital is only 15 minutes away and offers both specialty and subspecialty level services.

The applicant argues that offering specialty level at its facility would avoid the stress of transport to Carilion Roanoke Memorial Hospital. The application submitted evidence that infants often suffer both long- and short-term effects from separation from their mothers and neonatal handling and that infants have better outcomes due, in part, to skin-to-skin contact with the mother immediately after birth. It is true that an infant at an in-house NICU has an increased chance of bonding opportunities with the mother. These benefits, however, would apply only to patients born at LewisGale Medical Center if the project is approved.

As noted previously, LewisGale Medical Center provides 1.1% of its care as charity care. In the region, the average for all providers is 2.8%. It appears that the applicant would agree to a charity care condition, but I note that the project did not include any proposal to increase this level.

I also note the shift in position of the regional perinatal care center at Carilion Roanoke Memorial Hospital. The applicant has sought the introduction of specialty care services for several years, and each time the application has been opposed by that group. It does not, however, oppose the current proposal; and it also would staff the unit at LewisGale Medical Center, if approved. As stated previously, this fact is helpful in gauging public opinion but is not dispositive to the public need determination. Overall, I do not find any other factors remarkable enough to warrant using my discretion to grant the COPN.

C. The project does not provide any cooperative efforts to meet regional health care needs.[4]

The applicant submitted evidence that the physicians group at Carilion Roanoke Memorial Hospital would staff its proposed unit. The fact that LewisGale Medical Center would

[3] The adjudication officer stated that the bill was passed by the House of Delegates and continued into 2019. For clarity, the Commissioner notes that the bill did not pass, but was "passed by," i.e. continued to the next session.
[4] Va. Code § 32.1-102.3(B)(7)

contract with the same third-party company as Carilion to obtain neonatologists does not signify cooperative efforts to meet regional health care needs.

D. Overall, any benefits of the project are insufficient to demonstrate a public need for the project.

I generally agree with the adjudication officer's findings as to statutory factors 4, 5, 6, and 8. Va. Code § 32.1-102.3(B). Approval of the project would introduce institutional competition between LewisGale Medical Center and Carilion Roanoke Memorial Hospital.[5] The proposed project would somewhat reduce the number of admissions to Carilion Roanoke Memorial Hospital, but this would not reduce staff proficiency because the newborns would be cared for by the same neonatology physicians group.[6] The cost of the project is reasonable.[7] The project could present a site for educational opportunities because a member of the neonatology physician group is an assistant professor at Virginia Tech Carilion School of Medicine.[8]

Despite these benefits, the applicant does not demonstrate a public need for the project. These benefits do not outweigh the concerns regarding consistency with the SMFP, whether services are needed, and reasonable alternatives to the project.

III. Conclusion

Based on my review of the project, I am denying the project proposed by LewisGale Medical Center, LLC. The applicant has not demonstrated a public need for the project:

(i) The proposed project is not consistent with the SMFP;

(ii) The project would enhance the applicant's ability to increase its obstetrical admissions; however, this fact is not equivalent to increasing accessibility to specialty care for women with either high-risk pregnancies or their infants; and

(iii) The status quo is a reasonable alternative.

[5] Va. Code § 32.1-102.3(B)(4).
[6] Va. Code § 32.1-102.3(B)(5).
[7] Va. Code § 32.1-102.3(B)(6).
[8] Va. Code § 32.1-102.3(B)(8).

In accordance with Rule 2A:2 of the Rules of the Supreme Court of Virginia, any aggrieved party to an administrative proceeding choosing to appeal a case decision[9] shall file, within 30 days after service of the case decision, a signed notice of appeal with "the agency secretary." I would consider such a notice sufficiently filed if it were addressed and sent to the Office of the State Health Commissioner, and timely received by that office, at the James Madison Building, Thirteenth Floor, 109 Governor Street, Richmond, Virginia 23219. Under the rule, when service of a decision is "accomplished by mail," 3 days are added to the 30-day period.

Sincerely,

M. Norman Oliver MD

M. Norman Oliver, MD, MA
State Health Commissioner

cc: Stephanie Harper, MD, MPP
Director, Alleghany Health District
Vanessa MacLeod, Esq.
Assistant Attorney General
Deborah Waite
Virginia Health Information
Erik O. Bodin, III
Director, Division of COPN
Douglas R. Harris, JD
Adjudication Officer

Enclosure

[9] In accordance with Va. Code § 2.2-4023, the signed original of these final agency case decisions "shall remain in the custody" of the Department, while the applicants receive a photocopy of the original case decision letter.

RECOMMENDATION
TO THE STATE HEALTH COMMISSIONER
FOLLOWING AN INFORMAL FACT FINDING
CONFERENCE REGARDING CERTIFICATE
OF PUBLIC NEED (COPN or "Certificate")
REQUEST NUMBER VA-8391
LEWISGALE MEDICAL CENTER, LLC
Salem, Planning District (PD) 5
Health Planning Region (HPR) III
Introduction of Neonatal Special Care Services

I. Introduction

This document is a recommended case decision. It is submitted to the State Health Commissioner (hereinafter, the "Commissioner") for his consideration and adoption. It follows an informal fact-finding conference (IFFC) conducted in accordance with the Virginia Administrative Process Act (APA),[1] and has been written after a review of the Virginia Department of Health's (Department) administrative record of the above-referenced application for a COPN. This recommended decision follows the statutory criteria that the Commissioner must consider in determining whether to grant a COPN.[2]

II. Authority

Article 1 of Chapter 4 of Title 32.1 (§ 32.1-102.1 et seq.) of the Virginia Code (the "COPN law") addresses medical care facilities and provides that "[n]o person shall commence any project without first obtaining a [certificate] issued by the Commissioner."[3] The COPN law defines "project" to include the above-captioned proposal.[4]

III. Procedural Background

An IFFC on the project was held on June 18, 2019, in the County of Henrico. Principle agents of the applicant appeared and were represented by legal counsel. The applicant was given the opportunity to present evidence on the merits of its project through the submission of exhibits and the presentation of witness testimony. Through counsel, the applicant presented argument on the evidence.

A facilities planning analyst from DCOPN[5] attended the IFFC and presented that division's staff report on the project, dated October 19, 2018 (the "DCOPN staff report"). In the DCOPN staff report, that division recommends the denial of the project proposed by Lewis Gale Medical Center, LLC (LGMC), doing business as LewisGale Medical Center ("LewisGale"). Staff's recommendation of denial triggered the need for the June 18 IFFC.

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[1] Va. Code § 2.2-4000 et seq., *specifically*, Va. Code § 2.2-4019; *see also* Va. Code § 32.1-102.6.
[2] Va. Code § 32.1-102.3 (B).
[3] Va. Code § 32.1-102.3 (A).
[4] Va. Code § 32.1-102.1.
[5] DCOPN is the work unit, or division, within the Department that comprises the Commonwealth's professional health facilities planning staff.

At the close of the IFFC, a briefing schedule was devised for post-IFFC submittals. This gave an opportunity for the applicant to augment the adjudicatory record with written materials. The close of the adjudicatory record occurred on July 24, 2019.

The factual bases underlying the recommended decision made herein consist of evidence in the administrative record, including information in the application and responses to completeness questions from LewisGale, the DCOPN staff report, the transcript of the IFFC, and submittals made by the applicant's counsel subsequent to the IFFC. The current document discusses the most salient facts and argument made in relation to the proposed project, as it is gauged against the statutory considerations, below.

By reference, I hereby incorporate the DCOPN staff report into the present document for the limited purpose of establishing or corroborating basic and unrebutted facts and demonstrating, in part, analysis that may support or help substantiate the evidentiary basis on which the recommendation made herein rests.

Findings of Fact and Conclusions of Law

Based on the administrative record, I make and offer the following findings of fact and conclusions of law:

1. LGMC is a Delaware limited liability company, whose ultimate corporate parent is HCA Healthcare, Inc. LewisGale is a 506-bed tertiary-care hospital located in Salem, PD 5, HPR III.

2. LGMC proposes to introduce neonatal special care services with eight specialty-level bassinets (the "LewisGale project"). Total capital costs for the project are $5,420,100. These costs would be covered by internal reserves of HCA.

3. A. The Proposed Project in Relation to the Eight Statutory Considerations. Facts and conclusions about the project in relation to the statutory considerations include:

1. The extent to which the proposed service or facility will provide or increase access to needed services for residents of the area to be served, and the effects that the proposed service or facility will have on access to needed services in areas having distinct and unique geographic, socioeconomic, cultural, transportation, and other barriers to access to care.

LewisGale is an existing provider of obstetrical services and is licensed for 23 obstetric beds. The LewisGale project would increase access to needed services by allowing specialty level neonatology services to be provided at LewisGale. Approval of the project would improve outcomes and lower the number of infants who need to be transferred to Carilion Roanoke Memorial Hospital, in Roanoke, which is the regional perinatal center having subspecialty-level services.

Approval would improve continuity of care for mothers with high-risk pregnancies. Currently, pregnant women who are determined to be high-risk are directed to Carilion Roanoke Memorial Hospital. Approval would allow many expectant mothers to stay at LewisGale where they may

already be receiving care or where they have delivered children previously. Approval would allow continuous positive airway pressure (CPAP), catheters and higher dextrose intravenous fluids as well as other needed manners of care to be administered without transfer.

Transferring infants separates them from their mothers, impeding an important bonding process and initiation of the breast feeding process. Transferring infants also tends to truncate the postpartum hospitalization of mothers who want to be with their infants, putting them at risk for complications.

LGMC states that

> [a]lthough it is common knowledge in the community that [LewisGale] is a high-quality, tertiary-care, regional referral hospital, it is also well known that [LewisGale] does not provide neonatal special care services. As such, some patients do not even consider [LewisGale] as an option for delivery for fear of needing NICU [*i.e.*, specialty-level neonatal special care] services.[6]

By establishing a specialty level neonatal care service in a perinatal region that has none, the project would enhance access.

2. The extent to which the project will meet the needs of the residents of the area to be served, as demonstrated by each of the following:

(i) The level of community support for the project demonstrated by citizens, businesses, and governmental leaders representing the area to be served;

The LewisGale project enjoys an extraordinary, and perhaps unprecedented, level of public support, as evidenced by testimony at the IFFC on behalf of LewisGale by two state senators from the area,[7] letters from 11 state legislators, other local leaders, and Aetna. Further, an online petition with over 3,000 signatories shows strong and consistent community support. Many signatories to this petition related personal experiences and enthusiastic support for the project. The neonatologists who currently staff Carilion's subspecialty-level neonatology unit at Carilion Roanoke Memorial Hospital support the LewisGale project – which they would also staff. There is no known opposition to the project.

In 2018, legislation was proposed in the General Assembly, stating that the Commissioner "may issue a [certificate] for new specialty level neonatal care services located in Planning District 5 . . . ." This bill was passed by the House of Delegates and was continued to 2019 in committee on the expectation that LewisGale would pursue approval of the proposed project in the administrative process, and that the process may result in approval of the project.

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[6] LGMC Application at 11.
[7] Sen. John Edwards and Sen. David Suetterlein.

(ii) The availability of reasonable alternatives to the proposed service or facility that would meet the needs of the population in a less costly, more efficient, or more effective manner;

There are no reasonable alternatives to the LewisGale project. The proximity of the subspecialty level services at Carilion Roanoke Memorial Hospital does not make it a reasonable alternative for all situations. For example, LGMC states that

> [t]he [recent] death of a premature infant at Lewis Gale is a vivid reminder that Carilion's [subspecialty neonatal service] cannot meet all emergency needs. The simple fact is that Carilion's . . . transport services cannot be in two places at once. Furthermore, even when they are immediately available, the transfers consume valuable treatment time and are rife with risks, the majority of which could be avoided for most of the babies delivered at LewisGale.[8]

(iii) Any recommendation or report of the regional health planning agency regarding an application for a certificate that is required to be submitted to the Commissioner pursuant to subsection B of § 32.1-102.6;

No regional health planning agency exists to assist the Commissioner by making recommendations on applications for a COPN in HPR III.

(iv) Any costs and benefits of the project;

LGMC states that

> [t]he costs of the project are reasonable in light of the broad benefits of the project. Among other things, the project [would] reduce the number of unnecessary, risky, and stressful pre- and post-delivery transfers, improve institutional competition, and establish meaningful choice for patients throughout southwest Virginia.[9]

I agree. The project would increase continuity of care, facilitate better patient outcomes, reduce costs due to transfers and keep new families together during an already-challenging time. Even the neonatologists who practice at Carilion see benefit in approval. As one stated at the IFFC,

> [i]n an environment where seconds – rather than minutes – make a difference, an in-house provider will be able to provide the infant with an unexpected problem at delivery the needed intervention in a time frame that can decrease serious long term morbidities and mortality.[10]

If approved, LewisGale would be able to keep many infants needing special care in its own specialty level neonatal unit and avoid the stress of transport to Carilion Roanoke Memorial Hospital. LGMC also stresses that medical literature shows that "infants often suffer both long and short-term effects from separation from their mothers and from neonatal handling."[11] Infants have better

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[8] LGMC Proposed Findings and Conclusions at 17.
[9] *Id.*
[10] *Id.* at 5.
[11] LGMC Application at 12.

outcomes due in part to skin-to-skin contact with the mother immediately after birth."[12] These constitute direct benefits.

v) The financial accessibility of the project to the residents of the area to be served, including indigent residents;

LGMC has agreed to accept a charity care condition of 2.8 percent of gross patient revenues, and states it "is in compliance with all of its existing COPN charity conditions."[13]

(vi) At the discretion of the Commissioner, any other factors as may be relevant to the determination of public need for a project.

The Commonwealth has five perinatal regions. LGMC observes that

> [a]n examination of the [p]erinatal [r]egions reveals that . . . the availability of specialty-level NICU care is the standard of care everywhere else in the Commonwealth except [s]outhwest Virginia [*i.e.*, Perinatal Region 1]. Approval of specialty-level NICU services at [LewisGale] is necessary to provide patients in Perinatal Region 1 this same standard of care, and it is necessary to provide the same network of NICU services in place in most other [p]erinatal [r]egions.[14]

Approval of the LewisGale project would be consistent with certain approvals made over recent years.

Currently, babies born at LewisGale who need specialty and subspecialty care must be transferred to Carilion Roanoke Memorial. Disruption in continuity of care, as in the case of a transfer, can pose serious risks to babies and mothers. Such risks could be avoided if the Lewis Gale project is approved. This opportunity may be the most significant one and outweighs the risks of approval.

LGMC has sought the introduction of specialty care services at LewisGale for several years. In all previous attempts to gain approval of a certificate authorizing such, the regional perinatal care center at Carilion Roanoke Memorial Hospital has opposed it. It does not oppose the current project, and the neonatology physician's group that operates at that hospital supports the current project and, in fact, would staff the unit at LewisGale, as well.

No factors, other than those discussed elsewhere in this document, relating to the review of this project are clearly remarkable or appear to call for the exercise of the Commissioner's discretion in identifying or evaluating them in relation to the proposed project.

3. The extent to which the application is consistent with the State Medical Facilities Plan.

The COPN law requires that "[a]ny decision to issue . . . a certificate shall be consistent with the most recent applicable provisions of the State Medical Facilities Plan ["SMFP"] . . . ."[15] The

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[12] *Id.*
[13] LGMC Proposed Findings and Conclusions at 17.
[14] LGMC Application at 9.
[15] Va. Code § 32.1-102.3.

SMFP, found in the Virginia Administrative Code (VAC), beginning at 12 VAC 5-230-10 et seq., includes several provisions applicable to the project.[16] The most salient provisions are discussed here.

Driving Time. The SMFP calls for specialty and subspecialty neonatal special care services to be located within 90 minutes' driving time of hospitals providing general or intermediate level newborn services. Approval of the proposed project would not significantly increase access in this manner; however, it would provide a specialty level service to which other HCA hospitals in the area could directly refer infants.

Need for New Service. Because existing approved newborn units may add bassinets at will, the SMFP requirement that they should achieve 85 percent occupancy before a new specialty level newborn service should be added is meaningless and easily manipulated to show low occupancy. Of relevant units, the average annual occupancy of existing specialty level units is 87 percent.[17] The difficulty in applying this flawed provision has been recognized and discussed in previous recommendations, and is a known fault of the current SMFP.

Minimum Size of Unit. The SMFP states that specialty level newborn services should have a minimum of 18 bassinets. LewisGale is requesting approval of an eight-bassinet unit. LewisGale elicited testimony at the IFFC that an eight-bassinet unit is appropriate and well within the norm for existing specialty level units in Virginia and elsewhere. All but three of Virginia's 14 existing specialty level units have fewer than 18 bassinets.[18]

Further, the SMFP states that no more than four bassinets for specialty level services per 1,000 live births should be established in each HPR. LewisGale calculates a need for as many as 31 additional specialty level bassinets in HPR III.

Effect on Existing Services. The SMFP states that new services should not significantly reduce volumes of existing specialty level newborn services located within the applicable driving time. Approval of the project would not significantly reduce volumes at other providers, specialty-level or otherwise. There are no existing specialty level newborn services in the perinatal region, and the effect on Carilion Roanoke Memorial Hospital – a subspecialty neonatal care unit – should be minimal.

The Project under the SMFP Generally. After reviewing the administrative record, including the transcript of the IFFC, the DCOPN staff report, and the applicant's post-IFFC filings, I conclude that the project is generally consistent with the SMFP.

4. The extent to which the proposed service or facility fosters institutional competition that benefits the area to be served while improving access to essential health care services for all persons in the area to be served.

One of the goals of the project is to expand LewisGale's obstetrical program by removing a barrier to the decision of expectant women, who might be reluctant to choose LewisGale, for delivery. Approval of the proposed project would address that barrier and introduce institutional competition between LewisGale and Carilion Roanoke Memorial Hospital over specialty and intermediate-level

[16] 12 VAC 5-230-80, -490 through -510.
[17] LewisGale IFFC Exhibit 9
[18] LewisGale IFFC Exhibit 10.

nursery services and will increase competition over obstetrical services, without compromising the care and proficiency that comes with volume.[19]

5. The relationship of the project to the existing health care system of the area to be served, including the utilization and efficiency of existing services or facilities.

The proposed project would reduce somewhat the number of admissions for specialty and intermediate level nursery services to the regional perinatal center located at Carilion Roanoke Memorial Hospital without reducing staff proficiency. This reduction should be minimal; regardless, newborns with various levels of special care would be cared for by the same neonatology physicians group whether the birth occurred at Carilion Roanoke Memorial Hospital or LewisGale.

Approval of the project would bring the area affected more in line with other areas, including PD 15. All hospitals located in PD 15 (in Perinatal Region 3) that provide obstetric services have neonatal special care bassinets. No apparent harm to quality stemming from an abundance of these resources seems to occur in PD 15. In comparison, Perinatal Region 1 (which includes PD 5 and Salem) is the only perinatal region without a specialty level neonatal care service.

6. The feasibility of the project, including the financial benefits of the project to the applicant, the cost of construction, the availability of financial and human resources, and the cost of capital.

The cost of the project is considerable but within a reasonable range. The project stands to benefit LewisGale, known for being a tertiary care hospital that uncharacteristically lacks a specialty-level neonatal unit. Necessary resources for the project should be available or readily developed.

7. The extent to which the project provides improvements or innovations in the financing and delivery of health services, as demonstrated by: (i) The introduction of new technology that promotes quality, cost effectiveness, or both in the delivery of health care services; (ii) The potential for provision of services on an outpatient basis; (iii) Any cooperative efforts to meet regional health care needs; (iv) At the discretion of the Commissioner, any other factors as may be appropriate.

Insofar as the neonatology physicians group that serves the subspecialty-level unit at Carilion Roanoke Memorial Hospital would also operationalize the proposed project, it represents a cooperative effort to meet regional health care needs. At the IFFC, a member of the neonatology physician group that would continue to serve at Carilion Roanoke Memorial Hospital and begin serving at LewisGale stated that "[w]hen I work at Carilion, I don't work for Carilion. Similarly, I don't work for LewisGale, *I want what's best for the babies*. [Italics added.]"[20]

8. In the case of a project proposed by or affecting a teaching hospital associated with a public institution of higher education or a medical school in the area to be serve (i) the unique research, training, and clinical mission of the teaching hospital or medical school, and (ii) any contribution the teaching hospital or medical school may provide in the

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[19] LGMC Proposed Findings and Conclusions at 2.
[20] IFFC Transcript at 19.

delivery, innovation, and improvement of health care for citizens of the Commonwealth, including indigent or underserved populations.

A member of the neonatology physician group is an assistant professor at the Virginia Tech Carilion School of Medicine. The project could present a site for educational opportunities.

B. Conclusion.

Based on the findings of fact made above, and after a careful reading of the eight statutory considerations as a whole, I conclude that, approval of the Lewis Gale project would be reasonable and appropriate under the COPN law, as it would address a public need through a reasonable enhancement of existing services and bring an improvement in their accessibility.

V. Recommendation

Based on my assessment, I conclude that the Lewis Gale project merits approval. Lewis Gale should receive a certificate authorizing its project, subject to a charity care condition. The project is necessary to meet a public need.

In addition to conclusions drawn throughout this document, specific reasons for my recommendation include:

(i) The Lewis Gale project is consistent with the State Medical Facilities Plan;

(ii) The project would enhance accessibility, and promote reasonable utilization by incrementally adding necessary capacity;

(iii) The project is feasible and projected costs are reasonable;

(iv) No reasonable alternative to the project, as proposed, exists;

(v) Approval of the LewisGale project is a reasonable step in the maturation of neonatal care services in the area.

(vi) Extraordinary and knowledgeable public support for the project exists.

Respectfully submitted,

October 15, 2019

Douglas R. Harris, JD
Adjudication Officer